

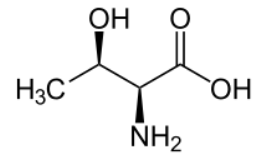
# L-THREONINE

## EP 9 INFUSION GRADE

PARAMETER	LIMIT
Appearance: White or almost white crystalline powder or colourless crystals	passes
Identity (A. Specific optical rotation/ B. IR)	passes
Test on turbidity (2.5 % (m/V) in H <sub>2</sub> O)	≤ Ref. Susp. I
Test on colour (2.5 % (m/V) in H <sub>2</sub> O)	≤ B <sub>9</sub>
pH-value (2.5 % (m/V) in H <sub>2</sub> O at 20°C)	5.0 to 6.5
Specific optical rotation (on dry basis) (6.0 % (m/V) in H <sub>2</sub> O at 20°C [ $\alpha$ ] <sub>D</sub> <sup>20</sup> )	-29.0° to -27.6°
Ninhydrin-positive substances (HPLC) <ul style="list-style-type: none"> <li>Each impurity</li> <li>Sum of impurities</li> </ul>	≤ 0.2 % ≤ 0.5 %
Ammonium	≤ 0.02 %
Chlorides	≤ 200 ppm
Sulphates	≤ 300 ppm
Iron	≤ 10 ppm
Loss on drying	≤ 0.5 %
Residue on ignition	≤ 0.1 %
Assay (on dry basis)	99.0 to 101.0 %
Total viable aerobic count	≤ 100 CFU/g
Moulds and yeasts	≤ 10 CFU/g
Salmonella	In 1 g n.d.
<i>Escherichia coli</i>	In 1 g n.d.
<i>Pseudomonas aeruginosa</i>	In 1 g n.d.
<i>Staphylococcus aureus</i>	In 1 g n.d.
Endotoxins (LAL-assay)	< 6 EU/g

### CHEMICAL DATA

Formula: C<sub>4</sub>H<sub>9</sub>NO<sub>3</sub>  
CAS Number: 72-19-5



### PACKAGING

25 kg Unit  
Outer container: Fiber drum  
Outer liner: HDPE  
Inner liner: LDPE

### STORAGE

Dry and dark at room temperature in tightly closed container

### STABILITY

Product is stable for 4 years from date of production if stored under recommended conditions in original packaging.